

REMARKS

Claims 26-28, 31-58, 67-70 and 73 were pending in the subject application. Applicants have herein amended claim 26 and added new claim 74. This amendment does not involve any issue of new matter. Entry of this amendment is respectfully requested.

Rejection under 35 USC § 102(b)

The Office Action rejected claims 26, 28, 31-42, 45-57 and 73 as allegedly being anticipated by Tracy et al. In response, applicants respectfully traverse this ground of rejection. First applicants point out that the controlled release compositions in Tracey et al. rely on a polymeric matrix to effect the release rate. For example, Tracey et al. defines “controlled release of interferon” as “sustained and/or modulated release of IFN from a biocompatible polymeric matrix.” *See* Tracey et al. column 2, lines 27-29. That same paragraph then states that “[i]n a sustained release, IFN release occurs over a period which is longer than that period during which a biologically significant amount of IFN would be released following direct administration of a solution of IFN.” *See* Tracey et al. column 2, lines 29-33. Therefore, the polymeric matrix described in Tracey et al controls the release rate of the IFN compositions described therein, because it states that solutions administered without the polymeric matrix would release over a shorter period of time.

In contrast, applicants’ claimed invention does not rely on a polymeric matrix to control the release rate. Applicants’ invention is based on the discovery that treatment of molecules, such as proteins, with organic compounds, can modify their solubility and thus, release rate. *See eg*, Applicants’ Specification, page 6, lines 21-23. The specification also states that the release is affected by the specific organic solvent used. *See* page 7, line 24. The specification further states that the rate of the controlled release can be modified based on, *inter alia*, the addition of organic solvent, time in the organic solvent, and concentration in the organic solvent. See page 10, lines 21-25. Applicants without conceding the correctness of the Examiner’s position but to expedite prosecution of the subject application, have herein amended the claims to clarify that the biopolymer’s exposure to the organic solvent results in the formulation’s sustained release properties, in contrast to the compositions described in the cited reference whose release rate is determined by a polymeric matrix. Thus, Tracey et al. does not anticipate the pending claims.

In addition, applicants note that new claim 74 has been added. The claim recites "consisting essentially of" and thus, would preclude the presence of a polymeric matrix as required by the cited reference. Thus, the cited reference does not anticipate the newly added claim.

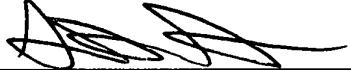
Accordingly, applicants contend that Tracy et al. do not anticipate the claimed invention. Applicants contend that these amendments and remarks obviate the above rejection and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945, under Order No. PBLI-P01-010 from which the undersigned is authorized to draw.

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Respectfully submitted,

By 

Spencer H. Schneider

Registration No.: 45,923

ROPES & GRAY LLP

FISH & NEAVE IP GROUP

1251 Avenue of the Americas

New York, New York 10020-1104

(212) 596-9000

(212) 596-9090 (Fax)

Attorneys/Agents For Applicant